

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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FEDERAL TRADE COMMISSION

Plaintiff,

v.

SHIRE VIROPHARMA INC.

Defendant.

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: C.A. No. 1:17-cv-00131-RGA  
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**OPENING BRIEF IN SUPPORT OF MOTION TO DISMISS BY  
SHIRE VIROPHARMA INC.**

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## **I. NATURE AND STAGE OF THE PROCEEDINGS**

On February 7, 2017, the Federal Trade Commission filed a complaint (“Complaint”) against Shire ViroPharma Inc. (“ViroPharma”) alleging monopolization in violation of section 5(a) of the FTC Act, 15 U.S.C. § 45(a). *See* D.I. No. 2. ViroPharma hereby respectfully moves to dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

## **II. SUMMARY OF THE ARGUMENT**

This action arises out of a petition that ViroPharma filed with the Food and Drug Administration (“FDA”) in 2006. ViroPharma’s “citizen petition” addressed the FDA’s standard for evaluating the bioequivalence of ViroPharma’s antibiotic Vancomycin Hydrochloride Capsules (“Vancocin”) – that is, the process for testing whether generic forms of Vancocin were appropriately safe and effective to be approved for sale to the public. The FTC’s Complaint openly acknowledges that ViroPharma’s citizen petition advocated that the FDA maintain the same standard for evaluating bioequivalence that the FDA had previously employed for a decade. The Complaint further acknowledges that the FDA evaluated ViroPharma’s citizen petition for more than six years, during which time the FDA modified its initial policy position, invited public comment, and convened two separate Advisory Committees comprised of independent experts to evaluate the issue. Moreover, information that this Court may consider at this stage, and which is referenced by the FTC in the Complaint, demonstrates that more than two years after the second of the two Advisory Committees had convened, and only five months before the FDA eventually denied ViroPharma’s citizen petition in 2012, the FDA publicly acknowledged that it had yet to rule upon ViroPharma’s citizen petition due to the complex scientific issues surrounding the bioequivalence standard. Nevertheless, nearly five years after

the FDA denied ViroPharma's petition and approved the sale of generic forms of Vancocin, the FTC filed this action asserting that ViroPharma's petitioning activity was anticompetitive.

The Court should dismiss the FTC's Complaint in its entirety for two reasons.

**First**, the FTC has failed to plead facts necessary for it to invoke its limited authority under section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to seek an injunction in this Court rather than pursue an administrative proceeding under section 5(b), 15 U.S.C. § 45(b). Congress granted the FTC the ability to file an action in federal court pursuant to section 13(b) only in limited circumstances where there is a need for immediate relief – in the express terms of the statute, where the defendant “*is violating*” or “*is about to violate*” the law:

Whenever the Commission has reason to believe . . . that any person, partnership, or corporation *is violating*, or *is about to violate*, any provision of law enforced by the [FTC] . . . the Commission . . . may bring suit in a district court of the United States to enjoin any such act or practice.

15 U.S.C. § 53(b) (emphasis added). However, no need for immediate relief has been pled here. To the contrary, the FTC's allegations confirm that the alleged conduct at issue ceased in 2012. There is no allegation that ViroPharma is currently violating the law, or is about to do so. The Complaint's conclusory and speculative allegations about what ViroPharma “*could do*” in the future, based upon what it allegedly did years ago, are insufficient as a matter of law.

**Second**, the conduct that the FTC alleges is unlawful is Constitutionally-protected petitioning activity that the *Noerr-Pennington* doctrine immunizes from prosecution under the antitrust laws. The facts alleged in the Complaint, even if true, would not justify an exception to the *Noerr-Pennington* doctrine. The FTC does not – and cannot – allege that ViroPharma's position was “objectively baseless.” The FTC's resort to an exaggerated counting exercise – adding up the individual filings in the citizen petition docket, and then double counting those filings with parallel filings that ViroPharma made in a separate docket in which the FDA invited

public comment – to suggest that ViroPharma engaged in a pattern of petitioning activity is unavailing. Regardless of whether ViroPharma’s conduct is viewed as a single petition (as it was) or a pattern (which it was not), the FTC has not alleged facts sufficient to meet its heavy burden under *Noerr-Pennington*.

Accordingly, the Complaint should be dismissed pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

### **III. CONCISE STATEMENT OF FACTS**

#### **A. The Parties And The Product**

ViroPharma previously owned and marketed Vancocin – an antibiotic used to treat potentially fatal intestinal infections. Compl. ¶¶ 30-31. ViroPharma became an indirect wholly owned subsidiary of Shire plc (“Shire”) in January 2014.<sup>1</sup> The Complaint does not allege that ViroPharma currently owns, manufactures or sells Vancocin.<sup>2</sup>

#### **B. The FDA Approval Process**

New drugs are required to undergo extensive testing designed to ensure their safety and efficacy. *Id.* at ¶¶ 10-11. The Hatch-Waxman Act allows the FDA, in appropriate circumstances, to approve generic versions of previously-approved drugs without separate safety and efficacy tests. *Id.* at ¶¶ 13-14. An applicant seeking regulatory approval to market a generic version of a previously-approved drug must file an Abbreviated New Drug Application (“ANDA”) with test results demonstrating that the proposed generic is “bioequivalent” to the brand drug. *Id.*

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<sup>1</sup> See Shire plc, Jan. 24, 2014 Report on Form 8-K, available at [https://www.sec.gov/Archives/edgar/data/936402/000095010314000457/dp43313\\_8k.htm](https://www.sec.gov/Archives/edgar/data/936402/000095010314000457/dp43313_8k.htm). The Court may take judicial notice of Securities and Exchange Commission filings when deciding a motion to dismiss. *See Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000).

<sup>2</sup> In fact, ViroPharma divested all rights and interests in Vancocin to ANI Pharmaceuticals in August 2014. *See* Shire plc, Oct. 24, 2014 Report on Form 8-K, available at: [https://www.sec.gov/Archives/edgar/data/936402/000095010314007381/dp50367\\_ex9901.htm](https://www.sec.gov/Archives/edgar/data/936402/000095010314007381/dp50367_ex9901.htm).

Bioequivalence is a statutorily-defined term that means “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action . . . .” *See* 21 C.F.R. § 320.1(e); Compl. ¶ 14. The appropriate study for establishing bioequivalence depends on the nature of the product, the purpose of the study, and the analytical methods available. *Id.* at ¶ 16. A gold standard for establishing bioequivalence has been *in vivo* clinical endpoint studies, which directly test whether the potential generic alternative is equally bioavailable at the site of action in a patient’s body. *See* 21 C.F.R. § 320.24(b) (describing *in vivo* end point studies as having among the highest levels of “accuracy, sensitivity, and reproducibility” of any method for “determining the bioavailability or bioequivalence of a drug product”). But the FDA will permit the use of other methods for establishing bioequivalence in appropriate cases. *Id.* Among the other types of studies that the FDA will permit in certain circumstances is *in vitro* dissolution testing, which compares the rate at which the innovator drug and potential generic dissolve in a solution. *See* App. Ex. 3, Response of the FDA to ViroPharma Inc.’s Citizen Petition, dated April 9, 2012 (“April 9, 2012 FDA Response”) at pp. 2-12 (referenced and relied upon in Compl. ¶ 104).<sup>3</sup>

### **C. Historic Bioequivalence Standards For Vancocin**

Vancocin is the brand name of vancomycin, a locally acting antibiotic that treats infections of the gastrointestinal tract. Compl. ¶¶ 30-31. The drug is not absorbed into the bloodstream, nor is it distributed systemically. *Id.* Given these unique characteristics, in 1996, the FDA issued a product-specific guidance for Vancocin requiring *in vivo* clinical endpoint

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<sup>3</sup> An Appendix of documents cited herein, all of which are referenced and relied upon in the Complaint, is submitted herewith and cited as “App.”

studies to establish bioequivalence (the “1996 Guidance”). *Id.* at ¶ 42; App. Ex. 3, April 9, 2012 FDA Response at pp. 22-23 (referenced and relied upon in Compl. ¶ 104).

In 2006, information became publicly available that suggested that the FDA, without providing public notice or the opportunity to comment, intended to assess bioequivalence of generic Vancocin based on *in vitro* dissolution testing, in direct contravention of the *in vivo* testing standard set forth in the 1996 Guidance. Compl. ¶ 47. The FDA’s change in position was purportedly based on the FDA’s conclusion that Vancocin was “rapidly dissolving” – a conclusion that the FDA later acknowledged was wrong in response to ViroPharma’s citizen petition. *See* App. Ex. 3, April 9, 2012 FDA Response at pp. 11-13 (referenced and relied upon in Compl. ¶ 104).

#### **D. ViroPharma’s Petitioning Activity**

##### **1. Citizen Petition**

On March 17, 2006, ViroPharma exercised its right to petition the FDA under 21 C.F.R. § 10.25(a), which expressly permits any “interested person [to] petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action” – referred to as a “citizen petition.” *See* 21 C.F.R. §§ 10.25(a); 10.30. ViroPharma’s citizen petition requested that the FDA (1) stay the approval of any ANDA for generic Vancocin capsules that did not comply with the bioequivalence standards from the 1996 Guidance, (2) explain the basis for its abrupt departure from its 1996 Guidance, and (3) provide the opportunity for public comment on the appropriate standard. *See* App. Ex. 1, Citizen Petition of ViroPharma Inc., dated March 17, 2006 (“Citizen Petition”) at pp. 1-3. In connection with this petition, ViroPharma submitted a number of filings to the FDA directed to the FDA’s change of policy. Many of these filings were either: (1) cross-filings of public comments submitted in

response to guidance about which the FDA provided notice in 2008 and solicited comment<sup>4</sup>; (2) formally memorialized points made in meetings with the FDA<sup>5</sup> (on some occasions at the FDA's request); or (3) the presentations (or descriptions of presentations) ViroPharma made as part of the Advisory Committee meetings in which the FDA solicited input and comments from the public.<sup>6</sup>

Despite regulations in effect when ViroPharma's citizen petition was filed in 2006, which required that the FDA respond to a citizen petition within 180 days, 21 C.F.R. § 10.30(e), the FDA did not respond to ViroPharma's citizen petition until April 9, 2012 – six years after it was filed. *See* Compl. ¶ 104.

## 2. Public Comment

In July 2008, more than two years after ViroPharma filed its citizen petition, the FDA convened a public meeting of an Advisory Committee to discuss bioequivalence methods for locally-acting gastrointestinal drugs such as Vancocin. *Id.* at ¶ 70. At this public meeting, ViroPharma presented its views, as did other companies that had filed applications with the FDA for the approval of generic forms of Vancocin. *Id.* In December 2008, the FDA issued draft guidance on the use of *in vitro* dissolution studies for generic Vancocin and solicited public comment. *Id.* at ¶¶ 71-72. The fact that the FDA had abruptly changed its position with respect to the bioequivalence standard for Vancocin in 2006, without promulgating draft guidance and affording an opportunity for public comment, was one of the concerns ViroPharma had raised in

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<sup>4</sup> *See, e.g.*, March 18, 2009 (Compl. ¶ 75); May 18, 2009 (Compl. ¶ 79); July 31, 2009 (Compl. ¶ 83); October 6, 2009 (Compl. ¶ 89); November 25, 2009 (Compl. ¶ 90); December 2, 2009 (Compl. ¶ 91); December 18, 2009 (Compl. ¶ 92); January 15, 2010 (Compl. ¶ 93); March 25, 2010 (Compl. ¶ 94); June 25, 2010 (Compl. ¶ 98); July 20, 2010 (Compl. ¶ 100); December 22, 2010 (Compl. ¶ 101); November 21, 2011 (Compl. ¶ 102); and December 22, 2011 (Compl. ¶ 103) filings.

<sup>5</sup> *See, e.g.*, January 11, 2008 (Compl. ¶ 65); and January 30, 2008 (Compl. ¶ 66) filings.

<sup>6</sup> *See, e.g.*, October 6, 2009 (Compl. ¶ 89) filing.

its citizen petition. *See* App. Ex. 1, Citizen Petition at p. 2 (cited in Compl. ¶ 54). In addition, in issuing its draft guidance in December 2008, the FDA accepted other arguments ViroPharma made in its citizen petition. In particular, the FDA agreed that Vancocin did not meet the definition of “rapidly dissolving” pursuant to the Biopharmaceutics Classification System (“BCS”) guidance, which had been the stated basis for the FDA’s policy change in 2006. Compl. ¶¶ 58, 72; *see also* App. Ex. 3, April 9, 2012 FDA Response at pp. 12-13. Additionally, instead of the wholesale acceptance of *in vitro* testing – the policy change that triggered ViroPharma’s citizen petition – the FDA proposed that dissolution testing for determining Vancocin bioequivalence should only be permitted where the inactive ingredients used in proposed generic alternatives were both quantitatively and qualitatively identical (referred to as “Q1Q2” sameness) to Vancocin. Compl. ¶¶ 70-72. Thus, nearly three years after ViroPharma had filed its citizen petition, the FDA had again altered its position.

In response to the 2008 draft guidance and the FDA’s invitation for public comment, ViroPharma filed submissions addressing the FDA’s new proposal for evaluating bioequivalence. At the prompting of the FDA, ViroPharma also filed its public comments in the citizen petition docket. *See* App. Ex. 2, Supplemental Citizen Petition Filing of ViroPharma Inc., dated January 11, 2008 at p. 1 (noting, “FDA confirmed that transparency and process were important to its mission, and FDA counsel requested that ViroPharma file the above-referenced comments on the Draft [Bioequivalence] Guidance to the Vancocin docket”).

In the summer of 2009, the FDA announced that it would once again convene an Advisory Committee to discuss, among other topics, the FDA’s dissolution guidance for generic Vancocin. Compl. ¶ 80. In preparation for this meeting, both ViroPharma and the FDA outlined their positions about the appropriateness of dissolution testing as a method for assessing

bioequivalence. *Id.* at ¶¶ 81-84. On August 4, 2009, the Advisory Committee convened, and by unanimous vote, advised the FDA of its view that *in vitro* dissolution testing could be used to establish bioequivalence to Vancocin if the proposed generic was Q1Q2 the same as Vancocin and certain other conditions were met. *Id.* at ¶ 85. The FDA did not rule upon ViroPharma's citizen petition until more than two and a half years later.

### **3. Freedom Of Information Act Requests**

In parallel with its citizen petition, ViroPharma made two requests to the FDA under the Freedom of Information Act ("FOIA") – one in March 2006 (after the FDA's initial policy change) and another in December 2008 (following the promulgation of the FDA's draft guidance). Compl. ¶ 110. In so doing, ViroPharma sought to obtain additional information about the FDA's proposed changes to the bioequivalence standard for Vancocin. Because the FDA did not respond fully to ViroPharma's request in its FOIA production, in December 2008, ViroPharma was required to file suit to compel FDA's compliance. *See ViroPharma Inc. v. HHS*, No. 1:08-cv-02189-PLF (D.D.C. Dec. 16, 2008). The FDA continued to resist complying with ViroPharma's FOIA request for nearly four years, with the FDA's most significant document productions not occurring until 2010. Compl. ¶¶ 110-12. In March 2012, the district court ruled in ViroPharma's favor, ordering the FDA to supplement its FOIA disclosures with additional information about the documents it withheld from its production. *Id.* at ¶ 112. Following the FDA's compliance with the district court's order, ViroPharma promptly withdrew its lawsuit. *Id.*

### **4. Precose Lawsuit**

In 2010, ViroPharma filed a declaratory judgment action relating to the FDA's approval of an ANDA for a different locally acting gastrointestinal product, Precose. Precose was not a ViroPharma product, but the standard applied by the FDA in approving the ANDA bore directly

on the Vancocin bioequivalence standard that was at issue in ViroPharma's citizen petition. *ViroPharma Inc. v. Hamburg*, No. 1:10-cv-01529-ESH (D.D.C. Sept. 10, 2010); Compl. ¶ 108. During the course of the litigation, the FDA admitted in court filings in November 2010 – more than four and a half years after ViroPharma submitted its citizen petition – that it still had not decided whether dissolution testing was sufficient to establish bioequivalence for proposed generic versions of Vancocin. The FDA also stated it was possible that it would accept ViroPharma's arguments that *in vivo* clinical endpoint testing should be required (as was the FDA's policy before 2006), and that no ANDA for generic forms of Vancocin had yet been approved. *See* FDA's Mot. to Dismiss at 11-12, *ViroPharma Inc. v. Hamburg*, No. 1:10-cv-01529-ESH (D.D.C. Nov. 12, 2010) (D.I. No. 13) (“[T]he agency's recommendations for vancomycin hydrochloride remain a work in progress. . . . FDA [is continuing] to evaluate its draft recommendation for the appropriate bioequivalence methodology for vancomycin hydrochloride.”) (footnotes and citations omitted). Relying on the FDA's representations, the district court concluded that ViroPharma lacked standing to challenge the FDA approval of the Precose ANDA. Compl. ¶ 114.

Similarly, in a November 21, 2011 filing with the United States Court of Appeals for the District of Columbia Circuit, more than five years after ViroPharma filed its citizen petition and two years after the 2009 Advisory Committee meeting, the FDA told the Court of Appeals that it was still considering whether *in vivo* testing should be required. Specifically, the FDA represented that it “ha[d] not yet made a decision on any of the [ANDAs] for vancomycin.” *See* Br. for Appellees at 36, *Viropharma, Inc. v. Hamburg*, No. 11-5143 (D.C. Cir. Nov. 21, 2011) (Doc. No. 1343328). Confirming the importance of the issues raised by ViroPharma's citizen petition, the FDA explained: “Whether FDA will ultimately approve an application will depend

on, among other things, complex, scientific determinations relating to the appropriate testing to demonstrate bioequivalence . . . .” *Id.*

On April 9, 2012, the FDA finally decided ViroPharma’s citizen petition. Compl. ¶ 104. On the same day, the FDA approved three ANDAs, as a result of which generic versions of Vancocin have been on the market for the past five years. *Id.* at ¶¶ 107, 140. ViroPharma is not alleged to have submitted any supplements to its 2006 citizen petition, or filed any other citizen petitions, since.

#### **IV. LEGAL STANDARD**

Dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6) is appropriate if the complaint fails to allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). While the Court must accept the complaint’s well-pleaded facts as true, it may wholly “disregard any legal conclusions.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). “In deciding a Rule 12(b)(6) motion, a court . . . consider[s] only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents . . . .” *Hartig Drug Co. Inc. v. Senju Pharm. Co. Ltd.*, 836 F.3d 261, 268 (3d Cir. 2016) (citation omitted).

Further, the plaintiff bears the burden of establishing the court’s jurisdiction. *See id.* at 272 n.14. Dismissal pursuant to Rule 12(b)(1) is appropriate if the complaint fails to allege facts that “plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right.” *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (citation omitted).

## V. ARGUMENT

### A. The FTC Has Failed To Plead Facts Necessary To Invoke Its Limited Authority Under Section 13(b).

The FTC's power to act is limited to the statutory authority delegated to it by Congress. *See Zola v. Interstate Commerce Comm'n*, 889 F.2d 508, 515 (3d Cir. 1989) ("The [FTC] is an administrative body possessing only such powers which are granted by statute." (quoting *Arrow-Hart & Hegeman Elec. Co. v. FTC*, 291 U.S. 587, 598 (1934))). The FTC brings this action pursuant to section 13(b) of the FTC Act. *See* Compl. ¶ 7. Section 13(b), however, only grants the FTC authority to file suit in federal court where a defendant *is* violating, or *is about to* violate the law. 15 U.S.C. § 53(b). In other words, to invoke the jurisdiction of this Court under section 13(b), the FTC must plead facts demonstrating either an *ongoing* or *imminent* violation of the law.

Here, the FTC has done nothing of the sort. The FTC does not allege that ViroPharma "*is*" violating the law; rather, the Complaint pleads that the conduct at issue ceased in 2012. The FTC also does not allege that ViroPharma "*is about to*" violate the law, much less plead facts that would support such a conclusion. Accordingly, the Complaint should be dismissed pursuant to Rule 12(b)(1) because the FTC does not have the authority to invoke the Court's jurisdiction, and Rule 12(b)(6) because the Complaint fails to allege facts sufficient to state a claim.

#### 1. The FTC's Section 13(b) Authority To Seek An Injunction In Federal Court Is Expressly Limited To The Need to Address An Ongoing Or An Imminent Future Violation Of Law.

In construing section 13(b), the Court need look no further than the plain language of the statute. *See Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001) ("Because it is presumed that Congress expresses its intent through the ordinary meaning of its language, every exercise of statutory interpretation begins with an examination of the plain language of the

statute. Where the statutory language is plain and unambiguous, further inquiry is not required.” (citations omitted)). Where, as here, Congress uses the present and future tense, the statute must be construed as reaching only those acts that are ongoing or will occur in the future, but not acts that were completed in the past. *See, e.g., Nat. Res. Def. Council, Inc. v. Texaco Refining & Marketing, Inc.*, 2 F.3d 493, 498 (3d Cir. 1993) (“[T]he undeviating use of the present tense strongly suggests . . . the harm sought to be addressed . . . lies in the present or the future, not in the past.” (quoting *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.*, 484 U.S. 49, 59 (1987))); *see also Dictionary Act*, 1 U.S.C. § 1 (“In determining the meaning of any Act of Congress, . . . words used in the present tense include the future as well as the present.”).

The conclusion that section 13(b) authorizes the FTC to seek injunctive relief addressing only ongoing or imminent future conduct is also compelled by the statutory structure of the FTC Act. Section 5 of the FTC Act proscribes as unlawful “[u]nfair methods of competition in or affecting commerce.” 15 U.S.C. § 45(a)(1). As relevant here, when faced with what it believes to be a violation of section 5, the FTC may proceed in one of two ways, depending upon whether the alleged conduct at issue occurred in the past, is still ongoing, or is about to happen. First, in the case of past or ongoing alleged conduct, under section 5(b), the FTC may initiate administrative proceedings against a party that the FTC has reason to believe “*has been* or *is* using” an unfair method of competition. 15 U.S.C. § 45(b) (emphasis added).<sup>7</sup> Second, in the case of ongoing or imminent future conduct, under section 13(b), where the FTC has reason to believe that an entity “*is violating*, or *is about to violate*” a provision of law enforced by the FTC

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<sup>7</sup> In the event that a violation is found and upheld by the Commission, subject to the right of the defendant to appeal to the federal Courts of Appeal, section 5 gives the FTC the power to issue a cease and desist order and, if necessary, to later enforce that order in district court. *See* 15 U.S.C. § 45(l) (“[T]he United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of . . . final orders of the Commission.”).

(including section 5), the FTC may file suit in federal court seeking to enjoin the ongoing or imminent violation. 15 U.S.C. § 53(b) (emphasis added).

That sections 5(b) and 13(b) serve wholly separate purposes is consistent with how the FTC has construed its statutory authority in the merger context. There, the FTC institutes section 5(b) administrative proceedings to review the legality of a proposed merger under the antitrust laws, and typically simultaneously seeks an injunction under section 13(b) in federal district court to block the merger pending completion of the administrative review.<sup>8</sup> Indeed, the FTC itself repeatedly has referred to its pursuit of injunctive relief under section 13(b) as a measure intended to “preserve the status quo.”<sup>9</sup>

Although it is not necessary to consider legislative history given the unambiguous terms of the statute, there is no doubt that Congress intended what it wrote. Before 1973, the FTC lacked the authority to initiate a civil proceeding of any kind in federal court with respect to alleged anticompetitive conduct. Its only procedural avenue was an administrative proceeding. *See United States v. JS & A Group, Inc.*, 716 F.2d 451, 452 (7th Cir. 1983). Given the protracted nature of the administrative process, however, section 5 was widely criticized at the time as inadequate.<sup>10</sup> In 1973, Congress addressed this problem by enacting section 13(b). *See* Pub. L. No. 93-153, § 408, 87 Stat. 592 (1973). As explained in a preceding Senate report, “[t]he purpose of [section 13(b)] is to permit the Commission to bring an immediate halt to unfair or

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<sup>8</sup> *See, e.g.*, Br. of the FTC at 2-3, *FTC v. Penn State Hershey Med. Ctr.*, No. 16-2365 (3d Cir. June 1, 2016) (Doc. No. 003112313990) (describing the FTC’s administrative complaint to block the merger of two hospital systems while, “[i]n the meantime, the FTC . . . asked the district court . . . to issue a preliminary injunction preventing the merger from closing before the administrative adjudication is complete”).

<sup>9</sup> *See, e.g.*, Pl.’s Mem. of Points and Authorities in Opp’n to Def.’s Mot. for a Scheduling Order and an Expedited Status Conference at 3-4, *FTC v. Inova Health Sys. Found.*, No. 1:08-cv-00460-CMH-JFA (E.D. Va. May 20, 2008) (D.I. No. 11) (describing the FTC’s decision to proceed under § 13(b) as “inherently limited in scope” and intended to “preserve the status quo until the FTC can perform its function”) (citations omitted).

<sup>10</sup> *See, e.g.*, David O. Bickart, *Civil Penalties under Section 5(m) of the Federal Trade Commission Act*, 44 U. Chi. L. Rev. 761, 762-63 (1977).

deceptive acts or practices when . . . [a]t the present time such practices might continue for several years until agency action is completed.” S. Rep. No. 93-151, at 30-31 (1973).<sup>11</sup>

Thus, the FTC Act’s plain language, structure, and legislative history establish conclusively that the FTC has no authority to pursue a federal court action in connection with conduct that occurred in the past. *See FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1089 (9th Cir. 1985) (“[T]he statutory language, legislative history, and cases indicate that § 13(b) may not be used to remedy a past violation that is not likely to recur.”).

**2. The Complaint Concedes That All Of The Challenged Conduct Occurred In The Past And The FTC Has Not Alleged That ViroPharma “Is” Violating, Or “Is About To” Violate, The Law.**

Here, exclusively invoking section 13(b), the FTC asks this Court to grant equitable relief based upon alleged conduct that the FTC itself acknowledges ceased long ago. The Complaint expressly alleges that the conduct at issue began in 2006 and concluded in 2012. *See* Compl. ¶ 49 (alleging conduct “[b]etween March 2006 and April 2012”); *id.* at ¶ 118 (“ViroPharma’s petitioning lasted over six years.”). Nowhere does the FTC allege that ViroPharma is currently engaged in any illegal conduct or that it “is about to” violate the law. That should end the inquiry.

At most, the Complaint alleges that ViroPharma *could* engage in anticompetitive conduct in the future. The Complaint’s allegations on the subject are limited to two short paragraphs:

Absent an injunction, there is a cognizable danger that ViroPharma will engage in similar conduct causing future harm to competition and consumers. . . .

Compl. ¶ 150.

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<sup>11</sup> The FTC itself explained at the time that it was seeking the power to enjoin *ongoing* violations of law. *See* 119 Cong. Rec. S21,445 (explaining that, in § 13(b), the FTC sought “the statutory authority to seek directly in the federal district courts preliminary injunctions against the continuance of anticompetitive conduct”) (letter from Ronald M. Dietrich, General Counsel of the FTC, to Sen. Henry M. Jackson, Chairman, Committee on Interior and Insular Affairs).

ViroPharma has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, ViroPharma marketed and developed drug products for commercial sale . . . and it could do so in the future. Consequently, ViroPharma has the incentive to obstruct or delay competition to these or other products.

*Id.* ¶ 151.

Even if these allegations were true, they would not be sufficient to trigger the FTC’s authority to file suit in federal court under section 13(b) because they say nothing about what ViroPharma is doing or is about to do. Moreover, these conclusory and speculative allegations about what ViroPharma “could do” in the future would be insufficient to support an injunction even if the FTC had the authority to bring this action. *See United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953) (a permanent injunction is appropriate where the moving party shows that “there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive”); *see also In re Plavix Indirect Purchaser Antitrust Litig.*, No. 1:06-cv-226, 2011 WL 335034, at \*4 (S.D. Ohio Jan. 31, 2011) (“[M]ere[] speculat[ion] that Defendants’ previous behavior . . . leads to the assumption that Defendants will engage in [similar behavior in the future]” is insufficient to survive a motion to dismiss); *FTC v. Home Assure, LLC*, No. 8:09-cv-547-T-23TBM, 2009 WL 1043956, at \*20 (M.D. Fla. Apr. 16, 2009) (the FTC’s showing of an anticipated future violation must “rise above a speculative level”). By parroting the “cognizable danger” language from *W.T. Grant Co.*, the FTC offers only a “formulaic recitation” of one of the elements it would be required to satisfy in order to obtain injunctive relief, which is patently insufficient to meet its pleading burden. *See, e.g., Hydrogen Master Rights, Ltd. v. Weston*, No. 16-474-RGA, 2017 WL 78582, at \*7 (D. Del. Jan. 9, 2017).

*FTC v. Merchant Services Direct, LLC*, No. 2:13-cv-00279-TOR, 2013 WL 4094394 (E.D. Wash. Aug. 13, 2013), is instructive. There, the FTC alleged that the defendants had

violated the FTC Act by misrepresenting the quality and price of the credit card processing services they offered to merchants. As here, all of the FTC's allegations concerned past conduct. *Id.* at \*3. The FTC sought to premise its right to relief on the allegation that “[a]bsent injunctive relief . . . defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.” *See* Compl. ¶ 40, No. 2:13-cv-00279-TOR (E.D. Wash. July 30, 2013) (D.I. No. 1). The court denied the FTC's request for injunctive relief, reasoning that the FTC had taken as a “foregone conclusion” that future violations would occur, but had proffered only “substantially outdated” and “stale” information concerning such alleged risk. *Merch. Servs. Direct*, 2013 WL 4094394, at \*3.

Similarly, in *Home Assure*, the FTC sought injunctive relief under section 13(b) based on allegations that the defendants had falsely promised customers that, in exchange for fees, they could help the customers avoid foreclosure. *Home Assure*, 2009 WL 1043956, at \*17. Again, the FTC's factual allegations solely concerned acts in the past. *Id.* Nevertheless, without elaboration or any factual predicate, the FTC asserted that the defendants were “reasonably likely” to engage in similar misconduct in the future. *Id.* at \*20. In denying the FTC's request for injunctive relief, the court found that the FTC's assertions “fail[ed] to rise above a speculative level.” *Id.*

These cases compel the conclusion that the FTC cannot establish a cognizable danger of an imminent violation of law merely by alleging past misconduct and asserting that history could repeat itself. As this Court recently recognized, allegations of fully completed conduct alone are insufficient to establish a right to seek an injunction. *See XpertUniverse, Inc. v. Cisco Sys., Inc.*, No. 09-157-RGA, 2013 WL 6118447, at \*12 (D. Del. Nov. 20, 2013) (“[A]n injunction is by definition a prospective remedy.”).

**3. The Complaint's Conclusory Allegations That a Future Violation "Could" Occur Is Refuted by the Facts Pled, A Change in the Law, And The FDA's Reports to Congress.**

Not only has the FTC failed to plead that a future violation is imminent, but there is ample basis for the Court to conclude at the Rule 12 stage that there is no plausible basis to believe that a future violation is likely to, or even *could*, occur. The FTC's allegations relate to *one* specific product (Vancocin) and principally to *one* specific issue (the unique testing required to establish bioequivalence for Vancocin). There is no basis to conclude that ViroPharma will file any citizen petition in the future relating to Vancocin or the methodology used to assure the safety of its generic alternatives. To the contrary, Vancocin has faced generic competition since April, 2012, Compl. ¶ 107, no citizen petitions are alleged to have been filed relating to that product in the ensuing five years, and ViroPharma no longer owns the rights to the product.<sup>12</sup>

Nor is there any basis to conclude that ViroPharma is predisposed to file an allegedly baseless citizen petition with respect to any other product or any other issue. ViroPharma is not alleged to have filed a single citizen petition (objectively baseless or not) with respect to any other product or issue during the six-year period that its Vancocin petition was pending, or in the five years since. After the alleged conduct at issue ceased, ViroPharma was acquired by and is now a wholly-owned subsidiary of Shire;<sup>13</sup> and, there is no allegation that any of the relevant individual decision makers at ViroPharma during the period at issue are still at the company or have the authority to direct the filing of citizen petitions with the FDA.

Moreover, and most significantly, the governing FDA statute was amended in 2007 to eliminate the risk of the very type of harm – delayed generic approvals as a result of citizen

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<sup>12</sup> See Shire plc, Oct. 24, 2014 Report on Form 8-K, available at: [https://www.sec.gov/Archives/edgar/data/936402/000095010314007381/dp50367\\_ex9901.htm](https://www.sec.gov/Archives/edgar/data/936402/000095010314007381/dp50367_ex9901.htm).

<sup>13</sup> See Shire plc, Jan. 24, 2014 Report on Form 8-K, available at: [https://www.sec.gov/Archives/edgar/data/936402/000095010314000457/dp43313\\_8k.htm](https://www.sec.gov/Archives/edgar/data/936402/000095010314000457/dp43313_8k.htm).

petitions – that is the FTC’s ostensible purpose for bringing this action and for seeking the requested injunction. In 2007, Congress amended the provisions of the Food, Drug, and Cosmetic Act (“FDC Act”) that govern the FDA’s approval of applications to market generic drugs.<sup>14</sup> Compl. ¶¶ 21-23. The amendments added Section 505(q), 21 U.S.C. § 355(q), which provides that the FDA “shall not delay approval of a pending application . . . because of any request to take any form of action . . . unless . . . the [FDA] determines . . . that a delay is necessary to protect the public health.” *Id.* at (q)(1)(A)(ii). Section 505(q) provides further that the FDA may summarily deny a petition if it determines that the petition was submitted with the “primary purpose of delaying the approval of an application and . . . does not . . . raise valid scientific or regulatory issues.” *Id.* at (q)(1)(E).

By virtue of these 2007 amendments, any citizen petition that ViroPharma might file in the future would not and could not pose a cognizable threat of improperly delaying generic approval. Notably, section 505(q) requires the FDA to report annually to Congress regarding the number of new generic drug applications the FDA approves and identify any delays resulting from the filing of citizen petitions. *See id.* at (q)(3). The FDA has published eight reports containing such data.<sup>15</sup> Those reports disclose that, from 2008 to 2015 – all of the years for which data is available – the FDA approved a total of 4,008 ANDAs and 505(b)(2) applications.<sup>16</sup> Of those 4,008 applications, the FDA has only identified *seven* instances in

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<sup>14</sup> *See* FDC Act, Pub. L. No. 110-85, 121 Stat. 954 (2007).

<sup>15</sup> *See* App. Ex. 4. The Court may appropriately consider the FDA reports in resolving this motion to dismiss, both because the reports are referenced in the complaint, *see* Compl. ¶ 23; *Astrazeneca Pharms. LP v. Apotex Corp.*, Nos. 10-338 et seq. (RBK/KW), 2010 WL 5376310, at \*9 (D. Del. Dec. 22, 2010) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)), and because as publicly-available reports of a government agency, the FDA reports are subject to judicial notice, *see Starks v. Coloplast Corp.*, No. 13-3872, 2014 WL 617130, at \*1 n.3 (E.D. Pa. Feb. 18, 2014) (FDA reports specifically); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) (published reports of administrative bodies generally).

<sup>16</sup> 505(b)(2) applications are applications for new drugs that rely on safety and efficacy tests performed in relation to other reference listed drugs, rather than directly on or for the applicant’s products. *See* 21 U.S.C. § 355(b)(2).

which ANDA approvals were delayed due to a citizen petition (excluding two ANDAs that were delayed because of citizen petitions filed by the ANDA filer itself, and one where the generic was enjoined from launching). That is just **0.175%** of all approved applications during the eight-year reporting period. In each instance, the FDA reported to Congress that the delay was necessary to “protect public health,” or used similar language. *See* App. Ex. 4, FDA Reports to Congress for Fiscal Years 2008-2015. The FDA has not reported **any** instances of delay caused by an objectively baseless citizen petition, and it has been abundantly clear since 2007 at the latest that the FDA has both the power and a statutory responsibility to avoid such a result.<sup>17</sup>

**4. The FTC’s Specific Prayer For Relief Further Demonstrates That The FTC Has Exceeded Its Section 13(b) Authority.**

Finally, the FTC’s broad, general request for an injunction in the Complaint’s prayer for relief – that ViroPharma be “permanently enjoined from engaging in similar and related conduct in the future” – confirms the complete lack of any basis to conclude that ViroPharma “is violating” or is “about to violate” the law. First, the fact that the FTC seeks only to enjoin ViroPharma from conduct “in the future,” rather than cease some activity that is occurring now, underscores that there is no ongoing violation alleged in the Complaint. Second, the complete lack of any specificity in the FTC’s prayer for relief confirms that the FTC has failed to plead the existence of a specific violation that is “about to” happen.

Indeed, given the absence of any specific ongoing or threatened violation, it is difficult to envision any injunction that this Court could issue that would satisfy Rule 65. *See* Fed. R. Civ.

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<sup>17</sup> In its reports, the FDA expresses a generalized concern about the impact that its responsibility to decide citizen petitions has on its ability to discharge its other statutory obligations. *See, e.g.*, App. Ex. 4, FDA Report for FY 2013 at p. 7. Such concerns about the adequacy of the FDA’s resources and how it should prioritize its work cannot be addressed through this lawsuit. Notably, in amending the FDC Act to include section 505(q), Congress chose not to limit the ability of pharmaceutical companies and others to petition the FDA, but rather to impose upon the FDA the responsibility of deciding those petitions promptly and to make it clear that the FDA has the authority to approve ANDAs regardless of whether a citizen petition is resolved, unless necessary to protect the public health.

P. 65(d)(1) (every order granting an injunction must “state its terms specifically; and describe in reasonable detail . . . the act or acts restrained or required”); *see also Louis W. Epstein Family P’ship v. Kmart Corp.*, 13 F.3d 762, 771 (3d Cir. 1994). That concern is particularly important here, because the conduct that the FTC targets is Constitutionally-protected petitioning activity and there is a heavy presumption against prior restraints.<sup>18</sup>

**B. ViroPharma’s Alleged Conduct Is Immune From Antitrust Challenge Pursuant To The Noerr-Pennington Doctrine.**

Separately and independently, the Complaint must be dismissed for failure to state a claim, because the petitioning conduct at issue is immune from prosecution under the antitrust laws.

“Those who petition [the] government for redress are generally immune from antitrust liability.” *Prof’l Real Estate Inv’rs Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) (“*PRE*”). This immunity, which is called the *Noerr-Pennington* doctrine based on the two cases that first recognized and articulated it, is grounded in the First Amendment’s right to petition the government. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135 (1961) (holding, “no violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws”); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) (explaining that “*Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose”). *Noerr-Pennington* immunity covers and protects the forms of petitioning the FTC challenges here: requests for administrative action and litigation. *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S.

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<sup>18</sup> *See United States v. Bell*, 414 F.3d 474, 478 (3d Cir. 2005) (“Permanent injunctions [barring speech] . . . are ‘classic examples of prior restraints’ . . .” (quoting *Alexander v. United States*, 509 U.S. 544, 550 (1993))); *Grove Press Inc. v. City of Phila.*, 418 F.2d 82, 89 (3d Cir. 1969) (“[P]rior restraint upon speech suppresses the precise freedom which the First Amendment sought to protect . . . [and] bear[s] a heavy presumption against . . . constitutional validity.” (citations and internal quotation marks omitted)).

508, 510 (1972). The Constitutional deference owed to petitioning activity is particularly broad in the context of administrative proceedings, such as the citizen petition process. *See, e.g., In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 686 (2d Cir. 2009).

There is a narrow exception to *Noerr-Pennington* immunity that arises where the petitioning activity “ostensibly directed toward influencing governmental action . . . is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.” *Noerr*, 365 U.S. at 144. For purposes of this so-called “sham” exception, the central question is whether a party uses the process of petitioning the government, as opposed to the outcome of that process, to harm a competitor. *PRE*, 508 U.S. at 60-61. A plaintiff seeking to rely on the exception “bears the burden of demonstrating that the challenged conduct was a sham.” *Trs. of Univ. of Pa. v. St. Jude Children’s Research Hosp.*, 940 F. Supp. 2d 233, 245 (E.D. Pa. 2013). The FTC has not pled a basis to apply the exception here.

# **1. The Standard For Pleading A “Sham” Is An Objective Standard.**

The standard for evaluating whether petitioning is a sham is an objective one. The subjective motivations of the Defendant to harm competitors or competition are irrelevant if the petition or petitions were instituted with “probable cause” to believe that there was some (even if small) chance of success. *See PRE*, 508 U.S. at 62 (“The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation.”); *Cal. Motor Transp.*, 404 U.S. at 512-13 (noting that a pattern of filing baseless lawsuits may be considered a sham, even if some proceedings prove to have some merit, if the overall pattern is to institute proceedings “without probable cause”). Probable cause to institute civil proceedings requires no more than a “reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication.” *PRE*, 508 U.S. at 62-63 (quoting *Hubbard v. Beatty & Hyde, Inc.*, 343 Mass. 258, 262 (1961) (alterations in original)). The “probable cause”

determination is inherently objective: the question is whether a “reasonable litigant” might believe there is a “chance of success,” rather than the subjective belief of the defendant.

The sham standard has been applied in slightly different ways depending upon whether the case involves a single proceeding or a pattern of petitions. When only a single proceeding is alleged to harm competition, *Noerr-Pennington* immunity applies unless the proceeding is “*objectively baseless* in the sense that no reasonable litigant could realistically expect success on the merits.” *Id.* at 60 (emphasis added). In pattern cases, courts have looked to whether there is a “pattern of baseless, repetitive” legal proceedings that “effectively bar[]” competitors from meaningful access to adjudicating tribunals, even if some of the proceedings prove to have some merit. *Cal. Motor Transp.*, 404 U.S. at 513.<sup>19</sup> Applying *California Motor Transport*, courts have held that it is not necessary in a pattern case to establish that every one of the proceedings was objectively baseless. *See, e.g., Hanover 3201 Realty, LLC v. Village Supermarkets Inc.*, 806 F.3d 162, 181 (3d Cir. 2015). However, it is still necessary to plead and prove that the overall pattern lacked objective reasonableness, *i.e.*, that the challenged proceedings overall were instituted “without probable case.” *See PRE*, 508 U.S. at 58 (discussing *Cal. Motor Transp.*, 404 U.S. at 512-13).

The Third Circuit addressed the circumstances in which a pattern of baseless, repetitive proceedings may constitute a “sham” in *Hanover 3201 Realty*, a case arising from efforts by a

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<sup>19</sup> In *California Motor Transport*, a group of trucking companies was alleged to have sought to drive “their competitors, including plaintiff, out of business [and] weakening such competitors” by instituting dozens of state and federal proceedings challenging licensing requests by the plaintiffs and other potential competitors. 404 U.S. at 511. The plaintiffs alleged that the process of responding to this multiplicity of proceedings was so onerous that “the machinery of the agencies and the courts was effectively closed to” them. *Id.* The Supreme Court made clear that harassment by lawsuit and administrative proceedings would lose its constitutional protection and be subject to antitrust challenge if it was used effectively to deprive competitors of their First Amendment rights to petition the government: “A combination of entrepreneurs to harass and deter their competitors from having ‘free and unlimited access’ to the agencies and courts, to defeat that right by massive, concerted, and purposeful activities of the group are ways of building up one empire and destroying another. . . . If these facts are proved, a violation of the antitrust laws has been established.” *Id.* at 515.

supermarket chain to obstruct construction of a competing supermarket. 806 F.3d at 166. There, the defendant initiated several different administrative proceedings and lawsuits against the real estate developer for the entering supermarket challenging various permits that had been sought and received by the developer. *Id.* at 167-70 (describing challenges to an already issued environmental permit, to requested wetlands and street permits, and a lawsuit challenging a zoning decision). The real estate developer was forced to defend against this “multifaceted” attack at great cost and inconvenience. *Id.* at 168.

Construing *California Motor Transport*, the Third Circuit held that “sham petitioning” may be found if “a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade.” *Id.* at 180. Although there are subjective aspects of this standard, the Third Circuit made clear that the central focus of the inquiry must be on whether the proceedings were “objectively baseless”:

If more than an insignificant number of filings have objective merit, a defendant likely did not have a policy of filing ‘willy-nilly without regard to success.’ A high percentage of meritless or objectively baseless proceedings, on the other hand, will tend to support a finding that the filings were not brought to redress any actual grievances.

*Id.* at 181 (citations omitted).

Here, although the FTC clearly seeks to position this as a “pattern” case, it plainly is not. ViroPharma only initiated a single citizen petition proceeding. As discussed below, the Complaint’s running count of filings made in that citizen petition proceeding – and the Complaint’s inclusion in its count ViroPharma’s public comments, FOIA requests, and lawsuits that could not have affected the timing of ANDA approval unless they were granted – are both misleading and legally irrelevant. Therefore, the *PRE* standard governs the FTC’s allegations,

and the FTC has not pled and cannot plead a basis for application of the sham exception in this case.

Even if this was a “pattern” case (it is not) and the *California Motor Transport* standard applied, the same result must follow. The FTC has not alleged facts that, if true, would establish that any relevant “proceeding” by ViroPharma was objectively without merit, much less that the entire course of its conduct was objectively baseless.

**2. The FTC Has Not Alleged That The Challenged Proceedings Were Objectively Baseless.**

First, the Complaint does not contain a single allegation that ViroPharma’s citizen petition or any single filing that it made was “objectively baseless,” much less – if viewed as a pattern – that a “high percentage” of the proceedings were “meritless or objectively baseless” or that the proceedings overall were “objectively baseless.” In fact, *the phrase “objectively baseless” does not appear anywhere in the Complaint.* This defect alone should be dispositive at the pleading stage.

Not only does the Complaint fail to allege objectively baseless petitioning expressly, but the facts alleged refute such a conclusion. As the Complaint acknowledges, the clearly stated goal of ViroPharma’s citizen petition was to “require generic applicants to conduct clinical endpoint studies” for Vancocin ANDA applications. Compl. ¶ 120. The FDA required *in vivo* clinical end point studies to assess bioequivalence for generic Vancocin capsules from 1996 until 2006, because Vancocin is a locally acting oral product with a site of action in the gastrointestinal tract. *Id.* at ¶ 43. ViroPharma simply sought (1) to maintain the status quo FDA policy, and (2) an explanation for the FDA’s sudden change in policy in 2006. *See* App. Ex. 1, Citizen Petition at pp. 1-3. Although ViroPharma ultimately did not convince the FDA to maintain its prior bioequivalence standard, the FTC has not alleged – and cannot allege – that the

citizen petition lacked objective merit. Indeed, the objective reasonableness of ViroPharma's petition is made plain by the FDA's own actions and public statements.

First and foremost, ViroPharma advocated in favor of a bioequivalence standard that the FDA had used for a decade. Furthermore, as the FDA itself acknowledged, the bioequivalence standard presented complex scientific issues that were not easily decided. As a result, despite a regulatory requirement to respond to the petition within 180 days, the FDA considered ViroPharma's citizen petition for more than six years. In July 2008, more than two years after ViroPharma had filed its petition, the FDA convened an independent Advisory Committee of experts to evaluate the bioequivalence standard for locally-acting gastrointestinal drugs, like Vancocin. Compl ¶ 70. Six months later, in December 2008, the FDA issued draft guidance regarding the Vancocin bioequivalence standard in which it revised its initial policy change in favor of a Q1Q2 dissolution standard and invited public comment. *Id.* at ¶¶ 71-72. In the summer of 2009, FDA convened yet another independent Advisory Committee to evaluate its recently-proposed draft guidance. *Id.* at ¶¶ 80-85. Although the Advisory Committee voted in favor of the draft guidance in August 2009, FDA still did not act on ViroPharma's citizen petition. Rather, it continued to deliberate. In November 2010, the FDA stated in court filings that its assessment of the bioequivalence standard "remain[ed] a work in progress" and that its evaluation was still on-going. *See* FDA's Mot. to Dismiss at 11-12, *ViroPharma Inc. v. Hamburg*, No. 1:10-cv-01529-ESH (D.D.C. Nov. 12, 2010) (D.I. No. 13). Similarly, in November 2011 – more than five years after ViroPharma filed its petition – the FDA advised the D.C. Circuit that it still had not made a decision "relating to the appropriate testing to demonstrate bioequivalence." *See* Br. for Appellees at 36, *Viropharma, Inc. v. Hamburg*, No. 11-5143 (D.C. Cir. Nov. 21, 2011) (Doc. No. 1343328).

Moreover, ViroPharma's petitioning was successful in certain key respects (a fact that bolsters ViroPharma's position here, but is not necessary for its conduct to be protected under *Noerr-Pennington*). Among other things, ViroPharma challenged the application of the BCS protocol to assess bioequivalence for generic Vancocin, a position that the FDA ultimately accepted. *See* App. Ex. 3, April 9, 2012 FDA Response at p. 13. The FDA also explained and elaborated on the scientific bases for its decision to allow bioequivalence testing for Vancocin based on *in vitro* dissolution studies, which it had not done until ViroPharma petitioned for that explanation. *Id.* at pp. 19-44. As courts in this district and throughout the Third Circuit have made clear, "litigation will not be considered a 'sham' so long as at least one claim in the lawsuit has objective merit." *Dentsply Int'l v. New Tech. Co.*, No. 96-272 MMS, 1996 WL 756766, at \*2 (D. Del. Dec. 19, 1996); *see also In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311-12 (E.D. Pa. 2011) (noting that conduct is not a sham if at least one claim in the petition has objective merit).

Put simply, where, as here, a petitioner is advocating for a position that the government had itself held for years, and the agency to which the petition is directed acknowledges the complexity of the issues presented, consequently convenes Advisory Committees of independent experts on two separate occasions, and admits in court that, after five years of study, it still has not decided the issue, there is no plausible basis to conclude that the petition was objectively baseless.

### **3. The FTC's Exaggerated Counting Exercise Does Not Add Up To A Sham.**

The FTC's attempt to establish the application of the sham exception based on the alleged number of ViroPharma's filings is meritless. The FTC goes to great lengths to provide a running count of the filings ViroPharma made in the citizen petition docket, in response to the FDA's

request for comments on its draft guidance, and in federal court. That counting exercise is the central (if not the only) support for the FTC's claims in this case. Compl. ¶ 118.

The FTC's arithmetic is flawed and misleading in a number of respects.

First, as discussed, there was only *one* citizen petition. It is both misleading and inappropriate to count each filing on the citizen petition docket as a separate "proceeding" for the purposes of applying the *Noerr-Pennington* doctrine. That is equivalent to arguing that every motion, response or other filing in a lawsuit should be considered a separate "proceeding" for the purposes of applying the antitrust laws, each assessed independently on its objective merits and its potential for affecting competition. That position is unprecedented in the antitrust jurisprudence and would, if accepted, create a cloud of potential antitrust liability over every litigation or administrative matter.

The courts have rejected attempts to count different parts of a litigation as separate proceedings for *Noerr-Pennington* purposes. In *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 413-14 (3d Cir. 2016), for example, the Third Circuit held that separate claims in a patent lawsuit are not separate "proceedings" for the purposes of applying *Noerr-Pennington* immunity. The Court properly recognized that "cases often involve claims of varying degrees of merit, many of which are weeded out . . . and it would be impractical to run a litigation system that made those kinds of claims subject to antitrust suits." *Id.* at 414. Other cases are in accord. *See, e.g., Luxpro Corp. v. Apple Inc.*, No. C 10-03058 JSW, 2011 WL 1086027, at \*5 n.1 (N.D. Cal. Mar. 24, 2011) (explaining that the court was not aware of any cases that support the notion that the court should count appeals as separate proceedings for purposes of assessing the applicability of the pattern exception); *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1360 (S.D. Fla. 2004) (even separate lawsuits can be treated as part of the same proceeding

where “they all involved the same patent and the same underlying legal issue”). “Petitions and motions filed within the same litigation or proceeding (i.e., lawsuit or administrative action . . .) are not counted as separate proceedings for analysis under either *PRE* or *California Motor Transport*.” *P.R. Tel. Co. v. San Juan Cable Co. LLC*, 196 F. Supp. 3d 248, 323 (D.P.R. 2016); *see also id.* (explaining that “the caselaw addressing the sham pattern theory has assessed the number of lawsuits filed, not motions or petitions filed within a lawsuit”).

Indeed, under the FTC’s approach, *PRE* itself would have to be viewed as a “pattern” case. *PRE* involved an allegedly sham lawsuit brought in federal district court. *See* 508 U.S. at 52. Despite the fact that the district court docket contained 164 distinct entries, including dozens of motions, memoranda, declarations, and other filings – many of which were made by the party alleged to have initiated the sham litigation – the Supreme Court treated the lawsuit as a single proceeding for purposes of its antitrust analysis. *See id.* at 60.

Second, the Complaint double-counts various comments that were submitted in response to the FDA’s requests for public comments and cross-filed on the citizen petition docket. Fourteen different filings are double-counted in this way, accounting for 28 of the 46 purported filings the FTC challenges. Compl. ¶ 118.

Third, the responses to the draft guidance were *solicited by the FDA*. *See id.* at ¶ 72 (stating, “[t]he FDA invited public comment for sixty days”). They are not proceedings instituted by ViroPharma. And, there are no allegations that those comments engendered delay or otherwise interfered with the competitive process in any way.

Fourth, none of the lawsuits about which the FTC complains are alleged to have adversely affected competition. In fact, the lawsuits could not have affected competition unless

the courts granted the relief ViroPharma sought, a type of competitive effect that is immune from antitrust challenge. *See, e.g., PRE*, 508 U.S. at 56-57.

Fifth, the vast majority of the filings at issue were made well before the earliest date that the FTC alleges that any ANDA for a generic alternative for Vancocin was even potentially approvable. The earliest date that the FTC alleges any ANDA was approvable is July 2010. *See* Compl. ¶ 147 (“[A]bsent ViroPharma’s exclusionary conduct, generic entry likely would have occurred by July 2010 – when Akorn’s ANDA was otherwise ready for approval – or even earlier.”). Thus, filings before that time could not have delayed generic entry except to the extent that they raised significant issues the FDA continued to consider over an extended period of time. Moreover, as the Complaint makes clear, ViroPharma made only three submissions on the citizen petition docket after July 2010, and there was an *eleven-month* period between December 2010 and November 2011 when ViroPharma made no filings. *Id.* at ¶ 118. If ViroPharma’s petition was truly objectively baseless, the FDA presumably would have denied it during that eleven-month period, or at any time during the six years that the petition was pending.

Accordingly, this Complaint challenging ViroPharma’s Constitutionally-protected petitioning activity should be dismissed pursuant to the *Noerr-Pennington* doctrine, for failure to state a claim.

## **VI. CONCLUSION**

For all of the foregoing reasons, the Complaint should be dismissed with prejudice.

Respectfully submitted,

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